UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re: MIRAPEX PRODUCTS LIABILITY LITIGATION.	File No. 07-MD-1836 (JMR/FLN)
	Minneapolis, MN September 10, 2007 11:00 a.m.

BEFORE THE HONORABLE FRANKLIN L. NOEL
UNITED STATES MAGISTRATE JUDGE

(PLAINTIFF'S MOTION TO AMEND COMPLAINT and ADD CLAIMS FOR PUNITIVE DAMAGES)

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(September 10, 2005, 11:00 a.m.)

THE COURT: This is what we now call In Re: Mirapex Litigation. Have I got that name correct? Let's get everybody's appearance on the record. For the plaintiffs.

MS. SUTTON: Tara Sutton and Gary Wilson on behalf of plaintiffs.

MR. BROWN: Good morning, Your Honor, Michael Brown on behalf of defendants, Pfizer, Inc., Pharmacia Corporation, and Pharmacia and Upjohn, LLC.

MR. SMITH: Your Honor, Scott Smith and Beth Rose for defendant, BIBI.

MR. PRICE: Your Honor, Joe Price, Faegre & Benson, for the Pfizer defendants.

THE COURT: Anybody else? Okay.

We're here on the plaintiff's motion to amend the complaint to add a claim for punitive damages. Ms. Sutton.

MS. SUTTON: Good morning, Your Honor. May it please the Court. Before the Court is plaintiff's motion to amend the complaints in the first 15 cases; they are known as the Selinsky cases to assert a claim for punitive damages.

The issue at this phase -- we're in the amendment phase, and it's whether plaintiffs are

entitled to assert a claim for punitive damages and whether or not the Court should permit the plaintiffs to present the evidence on punitive damages to the fact finder for determination.

The motion is governed by the amendment procedure that's set forth in Minnesota Statute Section 549.191. And the defendants agree in their brief with the plaintiffs that that statute is a procedural statute. And under Minnesota Conflicts of Law Analysis, the procedure of the forum is to apply.

So it's our position that that is the statute that governs this motion with respect to all 15 cases, because there are 12 cases in the Selinsky cases that are from out of state.

I'll get into more detail in the argument about defendant's claim that the Court should be considering the substantive law of punitive damages of the 12 out-of-state plaintiffs.

It's plaintiff's position that that's a question whether or not we are entitled to punitive damages. And we're not at that phase yet, we're just at the amendment phase. But in any event, with respect to most of the states with the exception of two, there's really no substantive issues before Minnesota law in the other states, so Minnesota law

would apply.

The Minnesota courts have found that the standard for punitive damages is met if you can show that a manufacturer has abused control over safety information or they have made misrepresentations about the safety of their product or they have used labeling that underestimates the risks of their product.

Plaintiffs have presented evidence in their brief and in the hundreds of exhibits that we have attached that not just one, but each of these types of conduct plus more is present here. From the day -- from the early days of Mirapex's drug development --

THE COURT: Let me make sure I'm following the argument. You're not suggesting that the standard is different in those situations, you're saying that each of those three way -- each of those things that you described are ways in which parties have demonstrated the deliberate disregard that the statute requires?

MS. SUTTON: Correct.

THE COURT: All right.

MS. SUTTON: And those cases are discussed on pages 43 and 44 of our brief. And in some of those cases, the Court has considered it sufficient evidence to allow amendment of the pleadings to assert punitive

damages. In other instances, this type of evidence is found to justify a jury's finding of punitive damages.

From the very early days of this drug development, defendants were aware that it would activate the area of the brain that was associated with motivation and reward. But what did they do? They basically did nothing. They failed to conduct adequate preclinical testing and then they put the drug into human clinical testing and they never even monitored for compulsive behaviors. But nonetheless, during the clinical trials, there were numerous reports of compulsive behaviors, including specific reports of gambling; someone who had a gambling addiction so severe, they tried to kill themselves while on Mirapex.

But what did they do with that information? They didn't change their labeling, they didn't apprise their clinical investigators, hey, be on the lookout for this behavior. And then after the drug is on the market, they continue to get reports. In the first published report they get of Mirapex being associated with gambling, what do they do? They void it from their safety database; they don't report it to the FDA. In fact, the evidence shows that it took them more than seven years after Mirapex was approved to

make any changes to their product label and then they buried the information.

They continue to deny causation in this courtroom, they deny causation to the public, even though internally their top doctors concluded years ago, that there was sufficient evidence for causation, they've withheld that conclusion in that report from the FDA, and now they're trying to hide behind what the FDA is saying.

I'm going to address each of these points in more detail, but we believe that all of this sets forth sufficient evidence to meet the prima facie standard of clear-and-convincing evidence that we're required to show at this phase.

From the very early stages of the drug development, it was no surprise to defendants that Mirapex could induce compulsive behaviors, in fact, it was expected. Mirapex was designed to target D3 receptors, and these are dopamine receptors in the brain. It was a unique compound, a compound that no other company had come up with yet, because of the fact that it activated the D3 receptor.

What is the significance of D3? Well, as this internal document from 1994 from defendant says, is that the D3 receptor is predominantly distributed

in the mesolimbic dopamine system, which is an area of the brain associated with reward and motivation.

It's been known since the 1980s that if activate this mesolimbic pathway, you encourage individuals to engage in behaviors that provide reward, such as food, sex, money, or ingesting drugs or alcohol. The pleasure that an individual feels from these rewards is reinforcing, meaning that you are going to want to do it again.

If the mesolimbic system is overactivated you can trigger an abnormal desire to seek these rewards, which in everyday life, translates into people engaging in compulsive eating, compulsive gambling, compulsive sex or in some cases, nicotine or alcohol or drug dependence.

In this connection between overactivation of the mesolimbic dopamine system was well known to the defendants and it was well known in the literature. And we've cited evidence dating back to 1994 that implicates the mesolimbic system in compulsive behaviors, including pathological gambling.

This isn't a -- the defendants know this and they try to claim in their brief that the role of the mesolimbic system was very complex and wasn't widely known at the time they were developing Mirapex. But

we got a report from one of their experts last week, Dr. Grant, who's a psychiatrist at the University of Minnesota. And he writes in page 11 of his report, that since 1980s, evidence has supported the role of the mesocortical limbic system in the mediation of reinforcing behaviors and rewards. So it was known to experts in the field what could happen if you trigger this system.

And when we took the deposition of Dr. Gordon, he was the pharmacology designee from BIPI, he said defendants knew from the very beginning that Mirapex could reinforce behaviors that seek pleasure. So, what did they do even though they knew the unique quality of Mirapex was to reinforce unique pleasure-seeking behaviors? Well, they basically did nothing; they abdicated their responsibility. They never undertook to ask in the clinical trials whether or not anybody was suffering from compulsive behaviors. They've admitted that. They said they never monitored for the behavior in their clinical trials. They didn't adequately test whether Mirapex could induce these behaviors.

In their brief, they say that there was a rat study that they did. And that's Exhibit N to their brief. It's a single rat study.

And I would encourage the Court to take a look at Exhibit N, because it's actually supportive of plaintiff's position. If you look at page 5 of the rat study, it says in this study they took rats who were cocaine addicted and they made Mirapex available to them. And what they found across all of the animals was, quote, a highly significant treatment affect. Meaning that Mirapex made the rats work harder to get their reward, their reward of cocaine.

This is exactly the contention that plaintiffs make in this litigation, that when you receive Mirapex, it increases your motivation to seek reward, and that can lead internally to compulsive reward seeking.

We also -- this was the end of their internal research from what we can tell. And this is the only research that they can point to that they did into this potential side effect. They also took steps to suppress any efforts by outside researchers to look into whether or not a D3 specific agonist like Mirapex could cause behavioral problems. They got a request from Dr. Torben Kling. He wanted to test Mirapex in what's called an intracranial self-stimulation model.

We got -- interestingly enough, we got another report from defendants last week from their

long-time consultant, and now expert in this case, James Bennett. And on page 10 of his report, he says if you want to figure out if a substance activates mesolimbic system and causes somebody to engage in rewarding behavior in an abusive manner, this is the kind of test you want to run.

But what did they do, they agreed jointly, both BI and Pharmacia, not to give the substance to their researchers. And this is a document that we got from the German production. This was a document that was secreted to Europe, but we were able to get in this litigation.

They say -- to explain this document, they say, well, the hypothesis of the study, the researcher wanted to look and see whether or not Mirapex dampened the reward -- the reward system. But they knew at this time, and as Dr. Gordon admitted, it would motivate people to seek pleasure. So it's perfectly understandable at this point if they don't want it implicated in the reward system, they wouldn't have given it to this researcher. That's exactly what happened.

Even though the defendants failed to monitor specifically for compulsive behaviors in the clinical trials, they received numerous reports. And we've

been able to piece together, just by looking at various reports, that there were at least 11 cases of compulsive behaviors in the clinical trial. Five of those 11 were people who engaged in gambling, and one of them is a person I mentioned who tried to kill herself because of her gambling problem.

The defendants, on the other hand, we haven't heard from them on what the final word on the number of cases is. They have the safety databases at their access. But all they've done is limited searching, across limited fields and limited studies. So there's at least 11, and there's probably more.

What's the significance of this? Well, there were 11 cases in the clinical trials. And when they heard about it during the clinicals, there was complete silence from the company. They never changed their label, they never apprised the clinical investigators to be on the lookout for this. And just contrast to this to what happened --

THE COURT: How many -- what was the sample size of the study?

MS. SUTTON: Several thousand.

But an example -- just to show you that 11 cases was significant, they did have one report during the clinical trials that somebody that suffered from

rhabdomyolysis, which is a condition that can injure the kidneys. If you can take -- usually if you can take the medication away, the condition reverses, much like you take Mirapex away, the gambling condition will reverse. When they got that single case, they put it in their labeling information, they put it in the precaution section. They reported a single case in a clinical trial was sufficient enough to get it in the labeling. 11 times more cases of compulsive behaviors, nothing.

So the drug, then, is launched in the U. S. market in late 1997. And they continue, after the drug is marketed, to get post-marketing accounts of compulsive behavior. And, in fact, in 2000, there were two researchers out of Arizona, their names Doctors Stacy and Samanta, they had it published -- presented a poster and then published an abstract of seven patients who suffered from pathological gambling while on Mirapex. The researchers reported that the gambling was severe enough to cause financial hardship.

Well, this report, Pharmacia admits they received it in August of 2000; BIPI claims they got it sometime later. But what happened? Pharmacia took the report, they entered it in their safety database

and then they immediately voided it. And that's the testimony of their witnesses, that it was voided, which meant they couldn't find it in their safety database anymore, and then they didn't have to report it to the FDA. And they didn't tell the FDA in August, 2000. Here they're claiming that Stacy has no relevance whatsoever to this litigation.

But three years later, Stacy reported these same seven patients in a journal and then he added an additional patient and also an account that somebody had tried to kill themselves because of Mirapex gambling. And what did they do in 2003? They then immediately reported it on a 15-day basis as a severe adverse event. But in 2000, they determined that it wasn't serious. But, in fact, it really was, because three years later they deemed it was.

And why did they not act in 2000? It may have had something to do with what happened to them in 1999. There was a case report of a similar eight patients on Mirapex who had a sleep attack while taking Mirapex. They advised the FDA and the FDA made them put a bolded warning on their label. They made them send a "Dear Doctor" letter.

In 2000 when they don't report it to the FDA, there's no signal, they're able to hide any

signal from the FDA and this case report. So there's no labeling action that's required.

THE COURT: Was there any impact on sales that you're aware of from the '99 sleep disorder report?

MS. SUTTON: You know, I'm not aware of that. We haven't gotten all of the numerical information concerning their sales because Your Honor denied our motion to compel on that matter until we established a claim for punitive damages. But I certainly think that it's probably fair to say that if a label -- at the time in 2000, none of the other dopamine agonists had any labeling pertaining to gambling. To add gambling to their label would have been an additional side effect that wasn't present for any other of the Parkinson's medications, and it probably could have had a market impact on them, and may have been part of the reason they didn't tell the FDA about it.

It takes basically until 2004 for the companies to do some internal assessment of the gambling issue with respect to Mirapex. In 2004, the top medical officers in charge of Mirapex worldwide, they were Doctors Zerban and Degner. They were charged to draft what's known as the Clinical Expert's

Statement, that's the title of the document, it's Exhibit 82. We've cited it to Your Honor before.

And in this report, they go through and they look at -- they analyze the reported adverse events of gambling on Mirapex. And when they do this, they don't even have all of the data, they don't have the five gamblers from the clinical trials, they only know of one gambler. So they do it on incomplete data.

But even with the incomplete data, they found the clear, pharmacodynamic effect of pramipexole -- and that's the chemical name for Mirapex -- on pathological gambling. And then they look at this data that's called D challenge data. And what D challenge data is, if you're on the drug and then they take the drug away and if the symptoms go away, it's called a positive D challenge; if the symptoms don't go away, it's called a negative D challenge. And what they found, is that there's mostly a positive D challenge. If you take Mirapex away, the gambling problem resolves.

And most of the defendant's witnesses, and we cite them all in our deposition, have admitted that D challenge data can be evidence of causation.

And they -- they again relied on this evidence to find that there was a strong effect of

pramipexole on gambling. And then they made a recommendation that there needed to be a change in the worldwide labeling for pramipexole. And they said, we need to say that gambling is a side effect, and we also need to tell people that the condition of gambling can improve if the drug is discontinued.

So, this -- Boehringer Ingelheim keeps what's known as a core data sheet. And all drug companies keep these core data sheets. And it's basically all of the information about the drug and what should be in the labeling of the drug or the drug worldwide. And the information is added to the core data sheet for Mirapex.

Now BIPI is saying that was a core data sheet for BI Germany, has nothing to do with us. But that's not true, because their company policy says that the company core data sheet is a reflection of the full knowledge of the BI company.

So it's our position that this is an admission that in 2004, that gambling was a side effect of Mirapex. And what does a side effect mean? And this is really crucial for this motion. The company operating procedure says, that you cannot list something as a side effect on the labeling or the core data sheet unless there is sufficient evidence of a

causal relationship.

So, pathological gambling being listed in the side effects means that in 2004, they determined that there was sufficient evidence of causation. So this goes out to all of the operating companies, including BIPI, and they are given instructions to add this kind of information to their label.

Well, what do they do? They submit a labeling change to the FDA in November of 2004, and at this time both Pfizer and BIPI are jointly marketing this drug in the U. S. They submit a labeling change in the fall of 2004. It doesn't get to the physicians and the Physician's Desk Reference, the PDR until June of 2005; it doesn't get distributed to them until much later.

What they do, here's all of the information that they add to the label (indicating). You can see it's way far down in the label. They just put it in the post-marketing experience. It's the barest mention of gambling. And the post-marketing experience section of the label is known in the drug industry as being the Siberia of the label.

If they had put in the information that it was recommended in the core data sheet, it would have had to have had a much more prominent place on the

label.

Instead, this is all that BIPI did, and they said, well, we didn't think the data supported the conclusions of the company.

But in March of 2006, they made another label change to Mirapex. And this time they heightened the pathological gambling information to the precaution section. It's still not in the warning section. They tell the physicians, if you discontinue the treatment, the condition is reversible. So you can see there's more information on the label. But it takes them more than a year from when it's recommended in Europe to do it here in the U. S., disregarding what we believe is the rights of the patients to know, if you have this problem on this drug, get off of it, it's going to go away.

The Clinical Expert Statement that we rely so heavily upon isn't the only internal admission of causation. These documents are all set forth in our brief. They've been admitting the mechanism by which Mirapex can cause gambling, and that there's causation for years. Pfizer in 2003 said that gambling while on Mirapex seems to fit within the dopaminergic model of OCD, obsessive/compulsive disorder, and the novelty reward model of dopamine. These two statements are

from the Degner statement .

BIPI says that the -- in 2004, the conclusions about causation aren't surprising considering how the drug acts. BI, when they learned that BIPI was telling the public that there wasn't a causal relationship, became quite alarmed. They write to them, they say, we do have an indication for a causal relationship and told BIPI to knock it off.

BI, again, another document saying gambling is a side effect. Again, as recently as 2006, they've found that there is evidence for a causal relationship between abnormal behaviors and Mirapex.

But despite the internal recognitions of causation, they've kept up a public relations campaign of misrepresenting their internal knowledge. They do it both in this courtroom and to the public.

November 2004, for instance, they told a CBS outlet that there were no cases of compulsive behavior in the clinical trials. They don't take that -- even in this litigation now, they don't take that position, they don't dispute the fact that we've found 11 cases of compulsive behavior in the clinical trials.

They said on NBC in February of 2005, that there was no scientific evidence of a causal effect. This is after they have the Degner report concluding

sufficient evidence of causation exists.

And they've continued -- we've taken depositions in this case where they still continue to deny that there's evidence of a causal association in this litigation.

And I just got -- I looked at my U.S.A. Today when I was travelling a couple of weeks ago, and they are quoted in the U.S.A Today saying that there isn't conclusive evidence of causation. So this campaign to misrepresent their knowledge about the affects of Mirapex continues to this day.

And now I want to spend some time addressing the October, 2006 FDA letter, because it's on the first page of their brief, and they have kind of made it the hallmark of their response to our motion.

And the letter from the FDA says that based on the available data -- the data that's available to them, they said that the available data doesn't support proof of a cause-and-effect relationship. But Judge Rosenbaum has looked at similar claims by drugs companies to hide behind the FDA and he's rejected this kind of tact, and the reason is very simple. He says the FDA has only a limited role in independently obtaining information about the safety of products; that that information is within the hands of the

manufacturer. And they're the ones with the duty to fully disclose the information.

And, in fact, in this October 2006 FDA letter, it goes on to say in a part they don't quote. The letter asks BIPI, give us all of your research on Mirapex and gambling, give us everything.

What did they do? They didn't give them everything. They haven't given them the Degner Clinical Expert Statement concluding causation. They haven't shown them all of the other documents where they've concluded that there's sufficient evidence for a causal relationship. They also have failed to disclose to the FDA all of the clinical trial cases they knew about of gambling. They admit in their brief that there were three cases of gambling that they never told the FDA about. They told the FDA about two cases. So there actually were two and a half times higher number of cases in the clinical trials than they told the FDA about.

Moreover, the FDA expressly made its conclusion and said it was just doing it on the information that was available to us. As Judge Rosenbaum has recognized, as oftentimes happens, the FDA doesn't have all of the information.

But, in any event, there doesn't have to be

proof of a causal relationship in order for a drug manufacturer to have a duty to warn its consumers. The FDA regulations are very clear on this. And this is regulation 201.57. And it specifically provides that a manufacturer has a duty to warn, as soon as there is reasonable evidence of an association, and explicitly rejects defendants argument that you need to have definitive evidence of a causal relationship. It says a causal relationship need not have been proven -- proved.

And one other point they make in their brief is, they say everyone has looked at this, including the FDA has rejected causal -- a causal association. That's not the case at all. In fact, every single piece of medical literature -- and it's all in our brief -- every single medical literature -- piece of literature has found that there is an association between Mirapex and gambling.

There's the September 2005 report from the Mayo. It says the relationship of pathological gambling to dopamine agonist therapy is striking and there's a particularly strong role for Mirapex.

There's a September 2006 study of 388 patients from Europe. And it says that the patients on Mirapex had a pathological gambling rate 25 times

higher than what you see in the general population.

The study from Valerie Voun in Canada, August of 2007, says there's a dose response relationship between Mirapex and pathological gambling; another thing you look at for causation.

And then just a few weeks ago there was a new study published, August of 2007, by consultants of BIPI, and they found that there was a tripling of the risk of engaging in impulsive behaviors while on Mirapex. Not even a doubling, but a tripling of the risk. So, really we're down to that their only criticism of the data, is that there hasn't been a controlled epidemiological study.

But the 8th Circuit, as Your Honor is probably aware in the Bonner decision said, you don't need epidemiology to prove causation -- legal causation.

In any event, defendants own experts and what's more damning for them, their expert consultants have been asking them, begging them, each time they get together, you need to run a controlled study. They started asking them to run a controlled study in 2003. What did they do? They drug their heels for year after year. They didn't even get a protocol together to run a study until 2006. That study isn't

going to be completed until 2009. Again, more evidence of their deliberate disregard for this issue and concerns for their patients that suffer from pathological gambling.

I'll quickly turn to the law, because plaintiffs submit that these facts are more than sufficient to establish a prima facie case of clear-and-convincing evidence and to allow this evidence to go forth to the jury.

Defendant's claim that the law of punitive damages of each plaintiff's home state should govern the motion. And we both have attached charts for Your Honor that set out the differences in the law. But their whole argument is premised on the notion that we are seeking from you entitlement or an award of punitive damages. But we're not at that phase yet, we're at the procedural phase of just amending our complaint.

THE COURT: And how does this work I guess procedurally? Let's assume I grant the motion and you get to allege it and you now have a complaint that alleges punitive damages and you get a case where the state law, which I assume at some point you agree does apply or --

MS. SUTTON: I think to the substantive

claim of entitlement to privilege -- to punitive damages, then there's going to be a conflict of laws analysis that has to be done; do you apply Minnesota law or do you apply the law of the underlying states? If there's no difference, and we submit that in about 11 of the states, the language is basically identical to Minnesota's language on the clear-and-convincing evidence and willful disregard; that at that phase, you can apply the Minnesota law because there's no conflict.

For a few of the other states, there's some minor differences, but we again think that the Minnesota law --

THE COURT: Is there any state that prohibits punitive damages outright?

MS. SUTTON: Right.

THE COURT: And how do you deal with that state?

MS. SUTTON: There are two states. The states are Louisiana and Massachusetts. It affects two cases; Thad Fayard's case is from Louisiana. Manny Quintela's case is from Massachusetts. We would suggest that -- and when you do your conflict of law analysis, and what we would argue is that Minnesota law should apply to those claims to allow punitive

damages to go forward under the better rule of law prong on the choice of law analysis; where Minnesota has a long-standing interest in providing relief from -- from when they've been -- when people have been injured, whereas they would been barred from that in their home states, and also Minnesota interests in deterring tortious conduct.

But if the Court would consider -- does consider these to be -- to block the claims of punitive damages, I think then we would be able to proceed in the 13 states that don't have the bar, in those two states we wouldn't proceed. But we don't think we're at that point yet, because we're at this procedure stage of just amending the complaint --

THE COURT: All right.

MS. SUTTON: -- and this could be dealt with on summary judgment.

THE COURT: Thank you.

MR. SMITH: Your Honor, we're going to divide it up and Mr. Brown is going to go first for Pfizer and I'll go for BIPI.

THE COURT: Okay.

MS. SUTTON: Do you want me to move those for you?

MR. BROWN: I can move them for you. I'm

also just going to hand some handouts to the clerk here.

MS. SUTTON: I don't want to be in your way.

THE COURT: Mr. Brown.

MR. BROWN: Good morning, Your Honor. As I indicated at the outset, I represent three separate companies, Pfizer, Inc., Pharmacia and Upjohn LLC, and Pharmacia Corporation, each of which had differing responsibilities with respect to Mirapex over various periods of time.

And as Mr. Smith said, he's going to talk about the roles and responsibilities that Boehringer Ingelheim Pharmaceuticals, Inc. had.

Before responding to the specifics of Ms. Sutton's comments, I think some context is important, especially when dealing with a motion to amend the complaint to add punitive damages, which I think everyone agrees is an extraordinary remedy reserved only for the most egregious of cases.

The context I'd like to talk about is number one, this drug, unlike many drugs that are the subject of MDL litigation, remains on the market and remains one of the most effective treatments for a very terrible disease, Parkinsons. And in litigations when the drugs are withdrawn from the market, plaintiff's

counsels embrace the FDA's role in drug oversight. But somehow today when the drug remains on the market, they're not quite as effective.

Again, just last November in 2006, more than a decade after the plaintiff suggests that everybody knew everything about all of the alleged problems this drug could cause, the FDA again determined that this drug was both safe and effective. And as Ms. Sutton said in October of last year, having received not only all of the published literature, all of the reports and the FDA database, and all of the information that they asked for and received from the companies, determined that there was insufficient evidence of a causal connection.

Now, plaintiffs today are suggesting that it's really just a question of association, but part of the big trump card has been that there has been allegations in the press from the company saying there was no causal connection, and Mr. Smith will talk more about that.

Now, whether the FDA is right that there isn't a causal connection, or whether the 20 expert reports that were delivered last Tuesday to Ms. Sutton's office where the experts say there was no causal connection and this information wasn't known,

whether they are right, I agree is something left for another day. But, however, Ms. Sutton indicated that Dr. Grant and Dr. Bennett had something to say on it, I would be happy to have the Court review Dr. Grant and Dr. Bennett's report when ruling on this motion.

But again, I think for contextual purposes, when we're talking about whether this is one of those egregious cases in which an extraordinary remedy should be allowed, I think the context I just provided suggests it's not.

Let me -- there are a number of factual and legal problems with the motion. Let me focus on the factual part first. Again, I'm going to focus more on those of the Pfizer defendants.

In looking at the timeline that I provided Your Honor, May 4th, 1990 -- actually, this involves BIPI and not any of the Pfizer defendants, but the plaintiffs have suggested that even at this very beginning stage, what they call the IND stage, the investigational new drug application stage, somehow the company is involved in conduct that would warrant this extraordinary remedy of punitive damages.

As the title says, this was the investigational stage of the drug. There were no answers at that point in time. The risk benefit

profile had not been determined and, of course, the drug had not yet been approved by the FDA as safe and effective. So to suggest that somehow something that was done back in the 1990 to '93 period, results in deliberate disregard or otherwise warrants punitive damages, frankly, is specious.

Second, with respect to the clinical trials --

THE COURT: Let me make sure I'm following now. As I understood their argument, it's not that it's something you did in 1990 that warrants punitive damages, it's what you knew in 1990, and based on that knowledge, what you did in the years following. That's the argument, isn't it?

MR. BROWN: Well, right. The argument is that -- exactly, that somehow something we either did or didn't do, based on information during this investigational stage. Again, the investigational new drug application and that entire process is completely regulated by the FDA.

So, again, at that point in time, people are -- even the companies when submitting an application are saying, we don't have all of the answers, we don't know all of the issues at this point in time, that's why they call it an investigational new drug

application.

With respect to the human clinical trials, I think everyone agrees also that those two are the exploratory phase, they are completely regulated by the FDA and, frankly, the plaintiffs just have their facts wrong again.

Today I've heard about 11 patients. In their brief, they're focusing on 18 patients of compulsive behavior. If you look closely, only five of which reported gambling, only one of which under the clinical trial regulatory definition standards, again, dictated by FDA, was it deemed by the independent investigator, not the companies, to be deemed serious.

The fact of the matter is, whether it's five or whether it's seven, or whether it's 11 or 18, frankly, doesn't really matter, because at the end of the day, once the FDA reviews all of the clinical trial data, they make a determination about whether or not, from a risk benefit standpoint, this drug is safe enough to go to the next step and ultimately be approved.

I want to talk next about what we'll call the Stacy abstract from 2000, where Dr. Stacy and Dr. Samanta first reported on case -- eight patients

that they had involving pathological gambling. This -- plaintiffs are suggesting that somehow that because of this two-paragraph poster that was presented in a conference in Spain, that this rises to the level of punitive damages, is simply beyond the pail.

The fact of the matter is, for months plaintiffs are suggesting that Pharmacia, which was a sponsor of the conference, somehow just missed the abstract. That's not true. It was forwarded to the Drug Safety Department, it was evaluated, and under regulatory criteria for determining whether or not it's a, quote, a serious report to report to the FDA, it was determined not to be a serious report and was, therefore, voided from the database.

This whole idea of voiding and offering some sort of conspiratorial aspect of it, there's a standard operating procedure plaintiffs have, of course, they don't mention it in their brief, that talks about the voiding process and what the criteria are for that.

So, it was evaluated. It was evaluated again later on by BI Germany, who did a very thoughtful analysis of this, and it was determined to be non-serious because, number one, all the patients were taking other medication including levodopa. Most

had other psychiatric conditions that were considered confounding factors, and while the company said, this is interesting and we should take a look at it, but this doesn't rise to the criteria of reporting it, so.

Plaintiffs then suggest that had it been reported, it would have sent a strong signal that would have resulted in a label change. But that's belied by the fact that when Dr. Stacy republished his paper in more detail with tables and other information, including one other patient that had a death involved, when that occurred, the FDA didn't require any label change at the time, and as Mr. Smith is going to talk about later, when the labeling was changed, and now for dopamine agonist the information is on there, Mirapex was the first, it voluntarily changed the label. It wasn't ordered to by the FDA.

And the suggestion that somehow that when the label changed with respect to sleep attacks, that that had something -- that's evidence of the fact that we weren't afraid to have a label change if need be, and no it didn't affect sales, because even today it's one of the leading treatments for Parkinson's disease and restless leg syndrome.

So the idea that somehow we were afraid to have a label change or have a "Dear Doctor" letter go

out is simply not true. We do it on the merits.

The fact of the matter is, that people are still debating very hotly and heavily today. As the FDA said, about whether or not this drug does or doesn't relate to impulse control disorders.

And the suggestion that Pfizer made an admission, it was on the list that it's -- it's similar to a model of OCD. Well, now the prevailing school of thought is, that it isn't even an obsessive/compulsive disorder, it's an impulse control disorder, which people think is different.

What they didn't say, was the person that wrote that e-mail that made its way up on the slide, explained it in full detail; that he was in no way admitting causation and he was asked the question directly. Do you think Mirapex causes pathological gambling? And he said no. So this idea that you take a phrase out of an e-mail and somehow that that's an internal admission, simply isn't the case.

But I think importantly, again, if you look at what did happen in August of 2003, and as of that point in time when they say everybody knew everything, as of August of 2003, the only patients in the published literature that had reports of Mirapex and pathological gambling were Dr. Stacy's eight patients.

Before that, there were a handful of other reports, none of which the patients were on Mirapex. So this idea that everybody knew back in 2000, or even back in the 80s and 90s, is simply not belied by the record.

So in August of 2003, what plaintiffs don't put in their brief is what Pfizer actually did to investigate. Number one, it reported the reports pursuant to the FDA regulations.

Number two, it conducted a worldwide literature search and, again, found that only Dr. Stacy's patients were the ones that had been on Mirapex and had any evidence of pathological gambling. And Dr. Stacy himself said in his reports, the incidents of pathological gambling in his patients was 1.5 percent, compared to the general incidents of pathological gambling of 1.3. What do you make of that? They're almost the same. Does that mean somehow somebody is hiding something or suppressing something?

The other thing Pfizer did, it called Dr. Stacy directly. It wasn't trying to hide anything, sweep it under the rug, it reached out to other experts and created expert panels to come in and talk about it, of which there was very robust debate about the whole thing. It prepared a written medical

response to the whole thing.

So, this is not the type of conduct that relates or suggests that the extraordinary remedy of punitive damages should be rewarded.

Lastly -- and Mr. Smith will talk about the expert report from BI Germany, an entity that is not a party to this litigation. But, again, from a factual standpoint, this is not the type of activity that warrants this extraordinary remedy.

So let me switch over to the legal issues for just a second. There were a host of problems with this. Number one, Mr. Smith is going to talk about what the standard is under Minnesota's practice but the choice of law issues are present and they're just glossed over. We have 11 different state's laws at issue here. Again, this isn't the first time the courts have been faced with this challenge. The Baycol MDL, the Guidant MDL. Not unexpected, we have a lot of people from other states other than Minnesota.

And Judge Davis, in his opinion, when talking about punitive damages, albeit in the class certification context said, the law of the state where the plaintiff resides is what's going to go. Again, Minnesota has no other connection on the punitive

damage side.

Again, here, as it relates to the Fayard and Quintela case, the motion clearly should be denied because there is no remedy of punitive damages under law of those particular states.

THE COURT: Why is the law of the plaintiff's residence apply as opposed to the law of the defendants?

MR. BROWN: Because that's most closely -- if you look at the choice of law analysis done in most tort cases, and certainly in most drug and device cases, they look to see where the alleged wrong took place, and that's generally where the plaintiff's reside, took the medication, and were treated. And virtually all of the cases like this will have the law.

Most recently, just a couple of months ago, that issue was briefed, argued in the Guidant MDL, for the first Bellwether case and Judge Frank decided that California law would apply. That's what Judge Davis came up with with respect to all the other Baycol plaintiffs. And, frankly, those were not groundbreaking rulings, they were very consistent with what other courts have done, and what should be done here. Again, there's really no nexus between these

out-of-state plaintiffs and Minnesota at all.

And if you look at any of those kinds of cases, they determine that sub -- that punitive damages are substantive, not procedural and, therefore, when ruling on this motion, the Court will need to go through the analysis as it relates to all 11 state's laws.

Again, I think that it's an easy exercise with respect to Mr. Fayard and Mr. Quintela, because those state's laws do not, period, allow punitive damages in a case like this.

Ms. Sutton said the rest of the states are all pretty similar. Well, frankly, they're not. We have five states that have a cap on punitive damages. That's significantly different than some of the other states. Some states when dealing with an FDA approved drug, like what we have here, have different rules about punitive damages, and have to do with whether or not information was or was not submitted to the FDA.

And again, you know, the center piece of plaintiff's argument has been that somehow, from clinical trials to other adverse event reports, that we didn't provide the information to the FDA. In addition to that being flatly wrong and rebutted in our opposition, that's essentially saying that we

either obtained or continued our approval of the drug based on defrauding the FDA.

I think even the plaintiffs would agree that that type of claim is barred by the U. S. Supreme Court's decision in Buckman v. Plaintiffs Legal Committee and the Minnesota Court of Appeals decision in Flynn v. American Home Products.

So, let me just wrap up that factually. Again, in this heavily regulated industry, the drug is still on the market as one of the leading treatments. It doesn't rise to the level of deliberate disregard in any respect. You add to that, the plaintiffs have not even attempted to do the analysis of choice of law and how this would work practically, plus the fact that these are heightened standards. I don't think the factual record in this case rises to the level of punitive damages under any statute, but they haven't even attempted to do that analysis.

With that, Your Honor, let me turn it over to Mr. Smith, who will talk about BIPI, as well as the Minnesota standard for moving to amend for punitive damages.

THE COURT: Okay. Thank you. Mr. Smith.

MR. SMITH: Thank you. Your Honor, may it please the Court, I have to admit I lost track of the

number of times that Mr. Brown said Mr. Smith would cover this.

MR. BROWN: Just twice.

MR. SMITH: If I forget anything, I hope someone slides me a note.

The Court, of course, is familiar with the Minnesota law regarding punitive damages. To summarize very briefly, the clear-and-convincing test applies to this motion. The plaintiffs must demonstrate a prima facie case that by clear-and-convincing evidence, these defendants, each on their own conduct, acted with a deliberate disregard for the rights or the safety of others.

And as the courts have told us, that's higher than willful indifference. And in the Emerson Tool case in particular, the Court said that is a high standard and is one that the Court should not rubber stamp. The Court went and looked at the information the plaintiffs brought before the Court to see, number one, is it accurate; and number two, does that information rise to the clear-and-convincing level? Does it rise to the deliberate disregard level that Minnesota cases say, even at this level, at this stage of the proceedings, must be met.

Now, I do want to focus on BIPI because

another thing I lost track of during the presentations before me, Your Honor, was the number of times that Ms. Sutton made use of the pronoun they. They did this, they did that, they didn't do the other. And I submit to the Court that this motion has to be judged on what each defendant individually knew, did or didn't do. And in that regard, I'd like to pass up -- counsel, thank you -- a chart showing exactly what BIPI's involvement with Mirapex was from 1990 when the first IND was submitted to the present time. Indeed, BIPI did submit the IND for Mirapex in 1990, and that starts off the process.

Now, as it happened, the FDA did not approve the IND for this drug until I think it was February of 1991. They placed what's called a clinical hold on this drug so that the clinical process wasn't allowed to begin until February of 1991.

But the important thing here is that as of February 16, 1993 -- and there's no dispute about this -- BIPI transferred the IND to the Upjohn Company. At that point, Your Honor, BIPI no longer had regulatory control over the development of Mirapex. And that was a -- that was nearly three years before Upjohn applied for the NDA. That's the final approval that allows the drug to be marketed and

approved by the FDA. That submission was made by Upjohn in December of 1995. BIPI had ceded away regulatory control nearly three years before the NDA application was made.

The importance of the 1993 date, in particular to this case, is that all of the information the plaintiffs complain about during the clinical trials occurred well, well after that date. Even if you take what they say as true -- and Mr. Brown I think gave very good reasons why the Court should not -- BIPI had ceded regulatory control by transferring the IND, at the time those events described by Ms. Sutton in 1995 and beyond --

THE COURT: But what's the point of that? In other words, as I said to Mr. Brown, as I understand the plaintiff's argument, it's not that because you or -- or Upjohn or anybody did something in 1990 or 1993, or failed to do something in 1990 or 1993 that you should have -- that they should be allowed to claim punitive damages. What they're saying is, stuff was learned during this period and then what you did and failed to do thereafter, even though you knew what was known in 1990 and 1993, that's what they say constitutes the deliberate disregard. Isn't that the argument or am I missing

it?

MR. SMITH: No, I think that is the argument in a sense, although the time went -- when it came time for BIPI to do something, that emerged in 2004. And I submit not earlier, because it wasn't until 2004 that BIPI then reassumed regulatory control over Mirapex when it acquired the NDA.

During that 11-year window from February of 1993 to January of 2004, BIPI was not in regulatory control of Mirapex. It wasn't involved with the reporting of adverse effects to the FDA, it wasn't involved with the labeling, it wasn't involved with the regulatory issues whatsoever until 2004 when it resumed regulatory control over the drug.

And again, all of the events -- I shouldn't say all, the great majority of the events -- and I'll talk about the ones that alleged to have occurred in 2004 and after. Those events between 1993 and 2004 did not occur when -- at a time when BIPI had regulatory control over Mirapex.

Now, just a couple things that the plaintiffs complain of during that time frame they say there was --

THE COURT: Let me make sure I'm following your argument though.

MR. SMITH: Sure.

THE COURT: What's the -- January 1, 2004 is the effective date that we're talking about when you did resume effective control over regulatory responsibility for Mirapex?

MR. SMITH: Yes.

THE COURT: Is it your contention that you are not responsible for things that were learned prior to that?

MR. SMITH: Let me give you an example. The plaintiffs say that in 2000, they, the defendants, learned of the Stacy abstract. Okay. That -- and by the way, that's patently false, because the record says that -- and it's clear from depositions, that BIPI was not at the conference, contrary to the allegation in their brief, and that BIPI did not learn of that Stacy abstract until 2003.

Nonetheless, it is clear from the regulatory scheme that's at work here, that the responsibility to report adverse events to the agency during this 11-year window is not BIPI's.

THE COURT: I understand that, but on January 1 of 2004 when the label is now yours, correct?

MR. SMITH: Right, right.

THE COURT: Is it your contention that if you say something on the label that's false or fraudulent or contrary to the facts that were learned between 1990 and December 31st and 2003, you're not responsible?

MR. SMITH: Let me answer that --

THE COURT: Just answer that question?

MR. SMITH: I am saying that as of January 1st, 2004, BIPI has regulatory responsibility, and things that are learned, things that BIPI is or should be aware of certainly go into the termination of what BIPI should do going forward.

In point of fact, Your Honor, and the evidence is clear on this, beginning in January, 2004, the same month that BIPI assumed -- or reassumed regulatory control over Mirapex, it put into the works that same month, a group to investigate whether or not there needed to be a labeling change to Mirapex. All right. That started the same month BIPI assumed regulatory control.

THE COURT: And is it your -- let me make sure I got it. It's not your contention, then, that everything that was learned from May 14th, 1990 to December 31st of 2003 didn't happen or you're not responsible for knowing about it? Is that a correct

statement?

MR. SMITH: I think -- I think what I'm saying is this: That certainly BIPI cannot be charged with deliberately disregarding the safety of users of Mirapex, and that's what this motion is about.

THE COURT: Let me just give you this example to make sure, because --

MR. SMITH: All right.

THE COURT: -- I think the question I'm asking is simpler than the one you're trying to answer.

MR. SMITH: Okay, that's happened before.

THE COURT: Let's assume that sometime between May 14th of 1990 and December 31st of 2003, that 88 percent of the people who take the drug die. Okay?

MR. SMITH: Okay.

THE COURT: January 1 of 2004, you become responsible for the label. Is it your contention that if you say on that date, gee, this is now my problem. Let's see, I'm going to investigate whether this drug is a problem and causes people to die.

Is it your contention -- strike that. It's not your contention, I assume from the answer I think I got so far, that you are not responsible for the

information that was generated, that 88 percent of the people who took it between May 14th of 1990 and December 31st of 2003 died? You would agree, would you not, that when it became your responsibility, you'd have to fix that label if it didn't say something about that, wouldn't you?

MR. SMITH: With the caveat that your hypothetical presents facts that are very different from those before the Court in this case, I think I would have to agree with the Court's position.

THE COURT: Okay.

MR. SMITH: And that is precisely, again, what BIPI did. They started the label-change process in January of '04. In February of '04, they submitted more adverse event reporting to the FDA. Again, since they held the NDA, that was now their responsibility. In April of '04, we're still talking '04, they convened a panel of expert scientists, world-renown expert scientists to figure out, what should we do, how much is here, what kind of signal are we getting on pathological gambling? Is it real, what's the relationship, what should we do with this? And by July of 2004 -- and again, this is clear from the record, it's in Plaintiff's Exhibit -- I'm sorry, it's in the Defense Exhibit W and X -- BIPI had decided to

make a voluntary label change and had produced language for that voluntary label change in July of 2004.

Now, the plaintiffs may say that wasn't fast enough, you should have done more sooner; that was six months. It certainly undercuts any suggestion, I submit, Your Honor, of deliberate disregard on BIPI's part for the safety of users of Mirapex.

THE COURT: Let me ask this question --

MR. SMITH: Sure.

THE COURT: -- because I'm not sure I see it on any of the timelines that you submitted, and it may be here. If it is, I apologize, just direct me to where it is.

When did the FDA first approve Mirapex as safe and effective and could go on the market?

MR. SMITH: I believe that was in 1996 or 1997.

MS. SUTTON: '97.

MR. SMITH: 1997, Your Honor. That was when the NDA that was submitted by Upjohn in December of 1995 was approved by the FDA.

MR. BROWN: Your Honor, on our chart, we actually don't have the approval, but July 2nd, 1997 when Pharmacia and BIPI entered into the co-promotion

agreement was the actually day of the approval. So once approved, they started co-promoting it.

THE COURT: So that's the same date? The co-promotion date corresponds with the FDA approval of the new drug application?

MR. BROWN: Correct.

THE COURT: All right. Go ahead.

MR. SMITH: Just, again, to focus on what BIPI did in 2004. In November of 2004, that's Plaintiff's Exhibit 86, BIPI actually filed with the FDA its changes being effectuated or CBE document putting into motion that label change in 2004. That was a voluntary act on BIPI's part. It was not required to do so by the FDA or anyone else.

In January of '06, BIPI approved the long-term study which we now know as the Dominion Study. In February of '06, again voluntarily, BIPI changed the label again to put the language regarding pathological gambling in the precautions section of the label, and also to add language regarding the fact that in some patients, discontinuance of the drug led to dechallenge -- that's their term, that's not the term on the label -- of the event. Again, voluntary on BIPI's part based upon its review of the evidence.

That, too, is completely and totally

inconsistent with a company that is acting in deliberate disregard for the rights and safety of others.

I do want to focus -- if I can take about ten minutes, I'd appreciate it, Your Honor.

THE COURT: Take about five.

MR. SMITH: Okay. On the three things that the plaintiffs really harp on, if you will, with regard to BIPI.

First is the Clinical Expert's Statement. This was a Clinical Expert's Statement that was done by BI Germany -- BI Germany, not BIPI -- in the summer of 19 -- of 2004, my error. And far from being an admission by BIPI, when BIPI received this, they said to Germany, we disagree, we don't think you have the science right. And ultimately what came out of that, was the exact language approved by Germany that went into the label change in the -- in November of 2004, in the CBE that was then effectuated. So, far from being an admission.

And I would submit, Your Honor, that anything that BI Germany does cannot, consistent with due process, form a basis for the imposition of punitive damages against BIPI.

The fact of the matter was, experts

disagreed on that and BIPI said, we think we're right, and Germany agreed on the form of the label, and that's what went into effect in November of 2004.

And if you look at --

THE COURT: Just again to make sure I'm following everybody's argument --

MR. SMITH: Okay.

THE COURT: -- the plaintiffs are not suggesting, as I understand it, that punitive damages be alleged and awarded because of anything BI did, it's because of what the BIPI response to the information that BI gave it? BI says, gee, this is a dangerous drug, you ought to do something about it.

What the plaintiffs are complaining about is not that, but that your response to that information is to say, oh, crap, that's not true.

That's what they're complaining about, isn't it?

MR. SMITH: I disagree with that, Your Honor. In part, they clearly are alleging punitive damages based on BI Germany's conduct. For instance, the 1994 discussion in their papers about this alleged agreement to suppress studies on addiction. If you look in the papers, that's all BI Germany, it is not BIPI. None of that, not one iota of that e-mail

exchange was discussions involving BIPI -- involves my client, BIPI.

Again, I submit they are seeking to impose -- if that's one of their bases for punitive damages, they are trying to saddle BIPI with punitive damages based on BI Germany conduct, and I submit that's constitutionally infirm, that cannot be done.

The FDA's letter of October, 2006. And if I -- this is Exhibit 92 from the plaintiffs, if I may hand this up.

THE COURT: Sure.

MS. SUTTON: It's important to note, Your Honor, that in October of 2006, to my knowledge, FDA had everything in front of it that the plaintiffs say it should have had, except perhaps for these three case reports that were not submitted in September of 2005. And I'll refer in the brief where Mr. Corsico -- or Dr. Corsico explained the reasons in his deposition why those three cases were not there.

Other than that, in 2006, to my knowledge, FDA had the post-marketing reports and had the published medical literature. And they say, we recently completed -- from the second paragraph -- a review of post-marketing reports and the published medical literature.

The only thing in terms of post-marketing reports they didn't have, to my knowledge, were those three cases. If they didn't have them and the published medical literature, we all had that.

And they say, although we feel that the available information does not constitute proof of a cause-and-effect relationship, we believe the evidence to be sufficiently strong to warrant the patients be informed.

Which is, in fact, exactly what BIPI did months earlier both in November of 2004, and again in 2006, in February. So when --

THE COURT: You've got about a minute left.

MR. SMITH: Thank you. So when the plaintiffs talk about this -- this willful and wanton public relations scheme to deny there is a cause-and-effect relationship, and when the FDA says, based upon the post-marketing reports and the published medical literature, we don't think there is a cause-and-effect relationship between pathological gambling and Mirapex, I submit, Your Honor, it cannot possibly, possibly be a deliberate disregard of the rights and safety of others when, in essence, the FDA is agreeing with BIPI's view of the strength of the causal relationship; the causal evidence that then

existed.

Your Honor, I suspect that there are many things that Mr. Brown promised I'd get to that I have not, I'll refer to those -- our legals in the brief.

THE COURT: All right. Thank you. Ms. Sutton, you have about thirty seconds.

MS. SUTTON: I want to address very briefly Mr. Smith's claim that BIPI should be absolved of any obligations with respect to Mirapex prior to 2004 when it became the holder of the NDA. He just must not understand the FDA regulations.

Not only were they involved in co-promoting the drug and profiting in the drug in the United States for the entire period of time that's alleged in the complaint, FDA regulations specifically provide that the safety reporting requirements apply not only to the holder of the NDA, but they also apply to anybody whose name is on the drug. BIPI's name was on the labeling of this drug at all relevant times. That regulation is 21 C.F.R., Section 314.80.

Mr. Brown says that we've glossed over choice of law, that we haven't dealt with it. It's dealt with at pages 34 through 42 of our brief. He says that you need to apply the substantive law of each state. He relies on the Baycol decision. Baycol

is a different procedural posture than this case.

It was on whether or not there was an entitlement to punitive damages, not whether or not it could be asserted in a complaint. But if they do want to take the tact that you should apply the substantive law of the individual states, I will say that in a number of the states at issue, you don't have to assert any level of proof in order to be able to amend your complaint to include punitives. In the states of Georgia, New Jersey, Ohio, Pennsylvania, Texas, Virginia, Wisconsin and California, you can assert punitive damages in the first instance, and the motion can be granted without even looking at the level of proof that we have submitted today.

And then finally, the FDA letter that he submitted to you, if you read down, it says in the second to last paragraph, it asks BIPI to provide the results of any research that you have performed related to this issue.

They -- it's undisputed that they have not, to this day, provided the Clinical Expert Statement that concludes for the BI company worldwide, including BIPI, that causation has been established.

MR. BROWN: May I have 30 seconds?

THE COURT: Only to answer my question,

which is this: What about on the choice of law question, the last point that Ms. Sutton made, which is, some states that don't require a showing of any level of proof before you can allege punitive damages. Why shouldn't they just be permitted to allege them as to the plaintiffs who reside in those states?

MR. BROWN: Well, I think, Your Honor, that -- and they created this situation of filing directly in Minnesota, and have gone from a procedural standpoint, that process to go about amending the complaint, but I think when you get to whether or not you then can meet the Minnesota standard about whether there's prima facie evidence of clear-and-convincing evidence, then the substantive law applies.

So, had these people filed in the state of their home jurisdiction and been part of the MDL, I don't think we'd be having this exercise. But they didn't do it that way, they filed directly in Minnesota, so I think they have to take -- use the procedural mechanism. But when making the determination, we then have to look at, all right, well, does this state even permit it?

Your Honor, may I have ten seconds on one other issue? And that's the Court asked about what was known -- you know, what the companies are

responsible for from what was known back in the 90s. Most of that has to do with this idea that the drug was addictive.

Slides 2 through 7 that I provided to you -- again, we dealt with this issue at the motion to --

THE COURT: I think I got your point.

MR. BROWN: -- fraud --

THE COURT: I think I understand your point.

MR. BROWN: It was to treat addiction, not cause --

THE COURT: I think I'm telling you you're done.

MR. BROWN: - it. Thank you, Your Honor.

THE COURT: Thank you. We're in recess.

* * *

C E R T I F I C A T E

I, Lorilee K. Fink, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

Certified by: _____
Dated: Lorilee K. Fink, RPR-CRR